

**REMARKS**

This Amendment responds to the Office Action mailed 15 October 2008. Claims 1, 28, and 45-48 are amended. Claims 50, 55 and 56 have been canceled without prejudice or disclaimer. Support for the amendments can be found variously throughout the application, including, for example the description at p. 4, lines 21-24. No new matter has been added. Accordingly, claims 1, 4, 5, 7, 12-16, 20-22, 24, 25, 28, 33-39, 45-49, 51-54 and 57-60 are presently pending in the application, each of which Applicants believe is in condition for allowance. Applicants respectfully request reconsideration of the application in light of the above amendments and the following remarks.

**Claim Rejections – 35 U.S.C. §112**

The Examiner rejected claim 56 under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 56 has been canceled rendering this rejection moot.

**Claim Rejections – 35 U.S.C. §103**

In the Action, the Examiner rejected claims 1, 13-16, 20-21, 28, and 45-60 under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 6,179,863 to Kensey et al. in view of U.S. Patent No. 6,626,918 to Ginn et al. Applicants respectfully traverse this rejection.

Independent claim 1 recites “a first indicator located at a proximal end of the dilator, . . . [and] a second indicator located at a proximal end of the insertion sheath.” Independent claim 28 recites “a first proximal hole located at a proximal end of the dilator, . . . and a second proximal hole located at the proximal end of the insertion sheath.” Independent claims 45 and 46 recite “wherein the first indicator is located in the dilator and the second indicator is located in the

insertion sheath.” Independent claim 47 recites “a first outlet port located at a proximal end of the dilator, . . . [and] a second outlet port located at the proximal end of the insertion sheath.” Independent claim 48 recites “wherein the first indicator is located in the dilator and the over insertion indicator is located in the insertion sheath.”

Kensey discloses two different positioning device embodiments 300, 400 that provide a vessel insertion indicator. The device 300 includes a port 304 defined in a sidewall 28B at a distal end of an introducer sheath 28. The port 304 is in fluid communication with a sideport 28D via a recess 302. The device 400 includes a port 404 defined in a distal end thereof. The port 404 is in fluid communication with the sideport 28D via a passageway 402. The port 404 is positioned distally beyond a distal end of the sheath. *See* FIG. 29.

There is no teaching or suggestion by Kensey of providing both the port 304 in the introducer sheath 28 and a port 404 distal of the introducer sheath in a single device. In contrast, the disclosure of Kinsey teaches away from such a combination of features. Both positioning device embodiments 300, 400 provide fluid communication between the inlet port 304, 404 and the sideport 28D. If both ports 304, 404 were combined in a single positioning device, the port 304 would be exposed to blood flow in the vessel first, thereby providing a flow of blood to the sideport 28D. Further distal insertion of the positioning device into the vessel would eventually expose the port 404 to blood flow in the vessel. However, since the port 404 is also in fluid communication with the sideport 28D, which continues to receive a flow of blood via the port 304, an operator would not be able to determine when port 404 has been exposed to blood flow in the vessel. Thus, the combination of ports 304, 404 according to the construction of devices 300, 400 of Kensey would be duplicative systems that provide no advantage and no benefit to the

operator. One of skill in the art reviewing Kensey would therefore be steered away from the combination of ports 304, 404.

Even if the ports 304, 404 of Kensey were combined, which Applicants submit would be illogical and not feasible, such a combination fails to disclose or render obvious the additional limitations of claims 1, 28 and 45-48 related to the outlet ports or indicators located at a proximal end of the device. Kensey discloses devices 300, 400 having inlet ports 304, 404 that are in fluid communication with a single sideport 28D. Kensey fails to disclose or suggest providing one of the ports 304, 404 being in fluid communication with “a first indicator located at a proximal end of the dilator” and the other of the ports in fluid communication with “a second indicator located at a proximal end of the insertion sheath,” as required by claim 1. Claims 28 and 45-48 include similar limitations as noted above, which limitations Kensey fails to disclose or suggest for at least the same reason.

Ginn fails to remedy the deficiencies of Kensey as it relates to claims 1, 28 and 45-48. Ginn merely discloses an obturator having a hole that is only positionable proximally relative to the distal end of the sheath. For example, Ginn clearly states that “sheath 12 may be advanced over a guidewire or other rail (not shown) previously positioned through the incision 92 into the blood vessel 90.” *See* col. 6, lines 40-44. As made clear in Ginn, sheath 12 is not inserted into a blood vessel using a dilator, but rather, sheath 12 is positioned in a blood vessel using a guidewire or rail that is already located in the blood vessel prior to introducing the sheath. Additionally, as clearly shown in FIG. 3, sheath 12 is positioned in blood vessel 90 without a dilator or even an obturator. *See* col. 6, lines 36-41 (“As best seen in FIG. 3, the sheath 12 may

be inserted or otherwise positioned within a blood vessel 90, *i.e.*, through an incision, puncture, or other opening 92 that extends from a patient's skin 94 . . .").

Ginn additionally discloses that an obturator is placed within the sheath only after the sheath has already been inserted into a blood vessel. For example, Ginn clearly describes that "[a]fter the procedure is complete, the device(s) may be removed from the sheath 12, and the obturator 14 inserted through the hemostatic valve (not shown) into the lumen 16 . . .". This passage in Ginn makes it clear that obturator 14 is not a dilator. The obturators in other embodiments disclosed by Ginn (*e.g.*, sheath 312 and obturator 314) also fail to meet the criteria of a dilator.

Even if the obturator 314 disclosed by Ginn were considered equivalent to a dilator, which would be highly improper, Ginn fails to disclose or suggest that the first side ports 342 is in fluid communication with "a first indicator located at a proximal end of the dilator" and that the second side port 350 is in fluid communication with "a second indicator located at a proximal end of the insertion sheath," as required by claim 1, or similar limitations required by claims 28 and 45-48. The ports 342, 350 are in flow communication with lumens 348, 352, respectively, within the obturator 314 and exit at, for example, proximal outlet 247, 251 of the obturator. There is no teaching or suggestion by Ginn of providing an outlet port for one of the inlet ports 342, 350 on the dilator and a separate outlet port on the insertion sheath. Therefore, Kensey and Ginn, alone or in combination, fail to disclose or render obvious every limitation of claims 1, 28 and 45-48.

Moreover, aside from the novel limitations recited therein, each of claims 4, 5, 7, 12-16, 20-22, 24, 25, 33-39, 49-54 and 57-60 are also allowable at least by virtue of their dependency

upon one of allowable base claims 1, 28, 45, 46, 47, and 48. Applicants respectfully request, therefore, that the rejection of claims 4, 5, 7, 12-16, 20-22, 24, 25, 33-39, 49-54 and 57-60 under 35 U.S.C. § 103 be withdrawn, and these claims also be allowed.

### Conclusion

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicants invite the Examiner to contact the undersigned attorney to expedite the handling of this matter.

Applicants expressly disclaim all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

Respectfully submitted,

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